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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,741	04/03/2001	Arthur W. Zikorus	VNUS-57380	4515

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FULWIDER PATTON LEE & UTECHT, LLP  
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EXAMINER

ROY, BAISAKHI

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/825,741

Applicant(s)

ZIKORUS ET AL.

Examiner

Baisakhi Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22, 35-41, 50-54, and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 35-41 and 50-54 is/are rejected.
- 7) ☒ Claim(s) 61 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/8/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

1. Claim 61 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Apparatus claim 61 should be dependent on apparatus claim 59 and not method claim 50. Since apparatus claim 59 was not elected, claim 61 is considered to be restricted under Species IV.
2. Claim 4 is objected to because of the following informalities: "a" fiber optic device should be replaced with "the" fiber optic device. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-15, and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn et al. (5830224).

Regarding claims 1 and 2, Cohn et al. disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction (col. 12 lines 4-7, col. 15 lines 14-32, col. 31 lines 50-53, claims 1, 2).

Regarding claims 3-7, Cohn et al. teach emitting light from a fiber optic device by introducing the catheter over a fiber optic device and removing the fiber optic device after the step of measuring the length of the device into the patient until the attribute of light changes (col. 25 lines 16-33, col. 27 lines 25-61).

Regarding claims 8 and 9, the reference teaches generating a magnetic field at the working end of the catheter and sensed by the catheter (col. 21 lines 64-67, col. 22 lines 1-63).

Regarding claims 10 and 11, the reference teaches introducing the catheter over a guide wire and generating a magnetic field at and by the guide wire (col. 23 lines 25-30 lines 47-67, col. 24 lines 1-18).

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Regarding claims 12-15, the reference teaches generating a radio-frequency signal at the catheter and sensed by the catheter (col. 20 lines 13-23 lines 40-47, col. 22 lines 42-63, col. 28 lines 50-67, col. 29 lines 5-51, col. 31 lines 11-15).

Regarding claims 19-22, the reference teaches generating an ultrasound signal at the working end of the catheter and sensed by the catheter and introducing the catheter over the guide wire with an ultrasound signal generated by the guide wire and sensed by the guide wire (col. 26 lines 4-65, col. 28 lines 1-11, col. 30 lines 28-36, col. 31 lines 9-28).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 35, 37, 38, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty et al. (6544230).

Regarding claim 35, Flaherty et al. disclose a method of positioning a catheter within a hollow anatomical structure by determining a desired location within the hollow structure, marking the location, introducing a catheter having a working end with a transducer into the hollow structure, identifying the location of the transducer, and positioning the working end of the catheter at the desired location within the structure (col. 3 lines 23-67, col. 6 lines 6-16 lines 60-67, col. 11 lines 6-22, col. 19 lines 9-43, col. 23 lines 1-33, and claims 1, 5).

Regarding claim 37, the reference teaches using a device to be controlled by the operator positioned over the hollow structure, which identifies the location of the transducer (col. 3 lines 23-60).

Regarding claim 38, the reference teaches generating a magnetic field at the working end of the catheter (col. 4 lines 20-47).

Regarding claim 40, the reference teaches generating an ultrasound signal at the working end of the catheter (col. 2 lines 41-55).

5. Claims 50, and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrul et al. (2004/0260333).

Regarding claim 50, Dubrul et al. disclose a method of positioning a catheter within a hollow anatomical structure by introducing a guide wire with a hook-shaped tip for hooking to the junction, introducing a catheter into said anatomical structure over the guide wire, and positioning the working end of the catheter proximate the junction identified in the hooking step ([0060] [0065] [0067] [0070] [0135] [0163] [0165] [0202-0205]).

Regarding claim 52, the reference teaches stopping the advancement of the catheter by a mechanical stop ([0089] [0100]).

Regarding claim 53, the reference teaches measuring the length of the guide wire introduced into the patient ([0089] [0100] [0108] [0109]).

Regarding claim 54, Dubrul et al. teach applying energy to the anatomical structure via an energy application device until the structure changes size ([0163]).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Dubrul et al. Cohn et al. teach the use of a guide wire but do not explicitly teach the hook-shaped tip. Dubrul et al. teach a method of positioning a catheter proximate to a junction in a hollow anatomical structure by using a hook-shaped tip located at the distal end of the guide wire ([0060] [0065] [0067] [0070] [0135] [0163] [0165] [0202-0205]). It would have therefore been obvious to one of ordinary skill in the art to use the hook-shaped distal tip teaching by Dubrul et al. to modify the teaching by Cohn et al. for the purpose of using said tip to engage the junction of the hollow anatomical structure.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Panescu et al. (5740808). Cohn et al. do not teach obtaining impedance

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measurements. Panescu et al. disclose a method of positioning a catheter proximate to an anatomical structure and measuring impedance (col. 26 lines 60-65). It would have therefore been obvious to one of ordinary skill in the art to use the impedance measurement teaching by Panescu et al. to modify the teaching by Cohn et al. for the purpose of measuring the impedance of the surrounding anatomy at the working end of the catheter.

9. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Goldberg et al. (5601580). Flaherty et al. teach the use of a catheter to identify a junction within a hollow anatomical structure but do not teach said structure to be the sapheno-femoral junction. Goldberg et al. disclose a method of positioning a catheter within a hollow anatomical structure such as the sapheno-femoral junction (col. 7 lines 30-57, claim 1). It would have therefore been obvious to one of ordinary skill in the art to use the sapheno-femoral junction teaching by Goldberg et al. to modify the Flaherty et al. teaching for the purpose of evaluating a hollow anatomic structure as the sapheno-femoral junction.

10. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Cohn et al. Flaherty et al. do not teach generating a radio-frequency field at the working end of the catheter. Cohn et al. teach a method of positioning a catheter within a hollow anatomical structure with the generation of a radio-frequency field at the working end of the catheter (col. 20 lines 13-23 lines 40-47, col. 22 lines 42-63, col. 28 lines 50-67, col. 29 lines 5-51, col. 31 lines 11-15). It would have therefore been obvious to one of ordinary skill in the art to use the radio-frequency teaching by



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Cohn et al. to modify the teaching by Flaherty et al. for the purpose of obtaining feedback from the catheter from a radio-frequency signal.

11. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Dubrul et al. Flaherty et al. teach the application of energy at the working end of the catheter (col. 5 lines 14-17) but do not teach applying said energy until the hollow anatomical structure assumes a smaller size. Dubrul et al. teach a method of positioning a catheter within a hollow anatomical structure with the application of energy at the working end of the catheter. It would have therefore been obvious to one of ordinary skill in the art to use the Dubrul et al. teaching regarding the application of energy to modify the teaching by Flaherty et al. for the purpose of reducing the size of the anatomical structure.

12. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. in view of Goldberg et al. Dubrul et al. teach the use of a catheter to identify a junction within a hollow anatomical structure [0135] but do not teach said structure to be the sapheno-femoral junction. Goldberg et al. disclose a method of positioning a catheter within a hollow anatomical structure such as the sapheno-femoral junction (col. 7 lines 30-57, claim 1). It would have therefore been obvious to one of ordinary skill in the art to use the sapheno-femoral junction teaching by Goldberg et al. to modify the Dubrul et al. teaching for the purpose of evaluating a hollow anatomic structure as the sapheno-femoral junction.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.R.

BR

  
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